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- (a) allantoin;
- (b) an emulsifier system comprising:
- (i) sodium stearoyl lactylate;
  - (ii) sodium isostearoyl lactylate;
  - (iii) optionally, triethanolamine;
  - (iv) optionally, at least one nonionic emulsifier selected from the group consisting of a nonionic emulsifier that is an ethoxylated ether or an ethoxylated ester whose carbon chain length ranges from 8 to 22 carbon atoms; and
- (c) an acid to adjust the pH to a range of from about 3.0 to about 6.0;
- wherein the composition is stable and effective over the pH range.

REMARKS

Claims 1, 3-5, 16, 18-22, 47 and 49-53 are pending in the present application.

The Office Action rejects claims 1 and 2 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,281,236. Claims 1-5, 16-22 and 47-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,329,413. Claims 1 and 4 are rejected under 35 U.S.C. § 102(b)

as being anticipated by U.S. Patent No. 3,954,989 to Mecca.

Claims 1-3, 16-17 and 20 are rejected under 35 U.S.C. § 102(b)

as being anticipated by JP 58-140013 (JP '013) to Minoru Kuroda

et al. Claims 1-3, 16-17 and 20 are rejected under 35 U.S.C. §

102(b) as being anticipated by U.S. Patent No. 4,806,262 to

Snyder. Claims 1-4 are rejected under 35 U.S.C. § 102(b) as

being anticipated by U.S. Patent No. 4,707,354 to Garlen et al.

Claims 1-5 and 16-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over JP '013 in view of U.S. Patent No.

4,767,618 to Grollier et al. and U.S. Patent No. 4,707,354 to

Garlen et al. Claims 1-4 and 47-50 were rejected as being

unpatentable over U.S. Patent No. 4,707,354 to Garlen et al. in

view of U.S. Patent No. 4,822,601 to Goode et al. and U.S.

Patent No. 4,184,978 to France. Claims 51-53 are objected to as

being dependant on a rejected base claim but would be allowable

if rewritten in independent form including all of the

limitations of the base claim and any intervening claims. These

rejections are respectfully traversed in view of the remarks

that follow.

By this Amendment claims 1, 16 and 47 are amended. No

new matter has been added by the amendments. Claims 2, 17 and

48 are cancelled without prejudice or disclaimer. It is

respectfully submitted that claims 1, 3-5, 16, 18-22, 47 and 49-

53 are in condition for allowance in view of the amendments and remarks presented herein.

**Double Patenting**

Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,281,236. Claims 1-5, 16-22 and 47-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,329,413.

The terminal disclaimer filed herewith obviates these rejections. Accordingly, withdrawal of these rejections is respectfully requested.

**Claim Rejections - 35 U.S.C. § 102(b)**

Independent claim 1 and dependent claim 4 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,954,989 to Mecca. The Office Action states that Mecca "discloses allantoin containing compositions in combination with an acid, such as ascorbic acid or citric acid, and an anionic surfactant such as Veegum K, at pH of about 4-4.5."

Mecca is directed to topical compositions containing an allantoin-ascorbic acid complex; each composition recited by Mecca includes both allantoin and ascorbic acid. Mecca also teaches a composition at a pH of about 4.0 to about 4.5 (i.e. a

discreet pH value).

Mecca, however, does not teach a composition comprising "allantoin; and at least one anionic or nonionic emulsifier that is substantially hydrophilic and is soluble in water; wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range," as recited in independent claim 1. Mecca further requires the presence of ascorbic acid and also teaches an allantoin-ascorbic acid complex in contrast to independent claim 1. Further, Mecca does not teach "wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range" as recited by independent claim 1. Finally, the Office Action asserts that Mecca teaches the use of Veegum K. Veegum K is the trade name for Magnesium Aluminum Silicate, Type II A. Veegum K is insoluble, but dispersible, in water. Thus, Mecca does not teach "at least one anionic or nonionic emulsifier that is substantially hydrophilic and is soluble in water" as recited in independent claim 1. Mecca, therefore, does not anticipate independent claim 1. Thus, withdrawal of the rejection of independent claim 1 under 35 U.S.C. §102(b) is respectfully requested.

Claim 4 depends from independent claim 1. It is

respectfully submitted that dependent claim 4 is distinguishable over Mecca for at least the same reasons described above and for the additional features it recites. Mecca, therefore, does not anticipate dependent claim 4. Thus, withdrawal of the rejection of dependent claim 4 under 35 U.S.C. §102(b) is respectfully requested.

Independent claims 1 and 16 and dependent claims 2, 3, 17 and 20 are rejected under 35 U.S.C. § 102(b) as being anticipated by JP 58-140013 (JP '013) to Minoru Kuroda et al. The Office Action states that Kuroda "discloses topical oil-in-water emulsions comprising allantoin, Carbopol 934 (carboxyvinyl polymer which is the same polymer as carboxypolymethylene) and optionally an anionic or non-ionic surfactant having a pH of about 5.5."

Kuroda discloses an allantoin containing composition having a pH of about 5.5. Kuroda, however, specifically indicates that if the topical composition as disclosed and claimed is "adjusted below pH 4, it is not desirable for the skin..." (Pg.6). Kuroda also states that results for the allantoin composition were excellent at approximately pH 5.0, but that "the allantoin content was found to be reduced a pH 6-7." (Pg. 6). In that regard, Table 2 in Kuroda (pg. 6) evidences a dramatic drop in allantoin concentration, and hence effectiveness, at a pH values

greater than 5. Consequently, the composition disclosed in Kuroda is only effective within a very narrow pH range. Kuroda does not teach a composition comprising "allantoin; and at least one anionic or nonionic emulsifier that is substantially hydrophilic and is soluble in water; wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range," as recited by independent claim 1. Nor does Kuroda teach a composition comprising allantoin; and an emulsifier system comprising: (i) an acidic anionic polymer; and (ii) an anionic emulsifier that is substantially hydrophilic and is soluble in water; wherein the pH of the composition is adjusted to a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range" as recited in independent claim 16. Furthermore, Kuroda specifically teaches away from the invention recited in independent claims 1 and 16 by indicating that the compositions taught by Kuroda are ineffective below a pH of 4.0 and have a reduction in allantoin concentration at pH values between 6-7. Kuroda, therefore, does not anticipate independent claims 1 and 16. Thus, withdrawal of the rejection of independent claims 1 and 16 under 35 U.S.C. §102(b) is respectfully requested.

Claim 3 depends from independent claim 1 and claim 20

depends from independent claim 16. It is respectfully submitted that dependent claims 3 and 20 are distinguishable over Kuroda for at least the same reasons described above and for the additional features they recite. Kuroda, therefore, does not anticipate dependent claims 3 and 20. Thus, withdrawal of the rejection of dependent claims 3 and 20 under 35 U.S.C. §102(b) is respectfully requested.

Independent claims 1 and 16 and dependent claims 2, 3, 17 and 20 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,806,262 to Snyder. The Office Action states that Snyder "discloses emulsions comprising allantoin, Carbopol, a nonionic surfactant and cetyl alcohol having a pH of about 4.5 - 8.5."

Snyder discloses a number of topical skin lotions. Under the heading of Optional Ingredients, Snyder states that "[t]he compositions should have a pH of from about 4.5 to about 8.5." (Col. 6, Ln. 46-47). Snyder does not, however, recite the exact pH value for any particular composition. Nor does Snyder disclose stability or effectiveness of any composition at any particular pH or over any range of pH values. Snyder does not teach any pH values below pH 4.5 or that the disclosed composition are stable and effective over a pH range encompassing values below pH 4.5. Snyder discloses only one

composition containing allantoin. (Example 1.). Snyder does not disclose a pH value for this composition or any range of pH values over which it is stable and effective. Snyder, therefore, does not teach a composition comprising "allantoin; and at least one anionic or nonionic emulsifier that is substantially hydrophilic and is soluble in water; wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range," as recited by independent claim 1. Nor does Snyder teach a composition comprising allantoin; and an emulsifier system comprising: (i) an acidic anionic polymer; and (ii) an anionic emulsifier that is substantially hydrophilic and is soluble in water; wherein the pH of the composition is adjusted to a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range" as recited in independent claim 16. Snyder also discloses "the compositions herein should be substantially free of anionic surfactants..." (Col. 6, Ln. 7-8). Thus, Snyder teaches away from the "an anionic emulsifier that is substantially hydrophilic and is soluble in water" recited in independent claim 16. Snyder, therefore, does not anticipate independent claims 1 and 16. Thus, withdrawal of the rejection of independent claims 1 and 16 under 35 U.S.C. §102(b) is



respectfully requested.

Claim 3 depends from independent claim 1 and claim 20 depends from independent claim 16. It is respectfully submitted that dependent claims 3 and 20 are distinguishable over Snyder for at least the same reasons described above and for the additional features they recite. Snyder, therefore, does not anticipate dependent claims 3 and 20. Thus, withdrawal of the rejection of dependent claims 3 and 20 under 35 U.S.C. §102(b) is respectfully requested.

Independent claim 1 and dependent claims 2-4 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,707,354 to Garlen et al. The Office Action asserts that Garlen "discloses compositions containing allantoin, a non-ionic emulsifier, emollients such as cetyl alcohol, vegetable oil, and various sunscreen, preservatives and acceptable topical carriers at a pH of approximately 5."

Garlen discloses an allantoin containing composition having a pH of "approximately 5." (Col. 4, Ln. 16). Garlen does not teach or suggest stability or effectiveness across any pH range or at any pH values above or below 5. Garlen, therefore, does not teach a composition comprising "allantoin; and at least one anionic or nonionic emulsifier that is substantially hydrophilic and is soluble in water; wherein the

pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range," as recited by independent claim 1. Garlen, therefore, does not anticipate independent claim 1. Thus, withdrawal of the rejection of independent claim 1 under 35 U.S.C. §102(b) is respectfully requested.

Claims 3 and 4 depend from independent claim 1. It is respectfully submitted that dependent claims 3 and 4 are distinguishable over Garlen for at least the same reasons described above and for the additional features they recite. Garlen, therefore, does not anticipate dependent claims 3 and 4. Thus, withdrawal of the rejection of dependent claims 3 and 4 under 35 U.S.C. §102(b) is respectfully requested.

**Claim Rejections - 35 U.S.C. § 103(a)**

Claims 1-5 and 16-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over JP '013 in view of U.S. Patent No. 4,767,618 to Grollier et al. and U.S. Patent No. 4,707,354 to Garlen et al. Claims 3-5 depend from independent claim 1 and claims 18-22 depend from independent claim 16.

As discussed above, JP '013 (Kuroda) discloses an allantoin containing composition having a pH of about 5.5. Kuroda, however, specifically indicates that if the topical composition as disclosed and claimed is "adjusted below pH 4, it is not

desirable for the skin...." (Pg.6). Kuroda also states that results for the allantoin composition were excellent at approximately pH 5.0, but that "the allantoin content was found to be reduced at pH 6-7." (Pg. 6). In that regard, Table 2 in Kuroda (pg. 6) evidences a dramatic drop in allantoin concentration, and hence effectiveness, at a pH values greater than 5. Consequently, the composition disclosed in Kuroda is only effective within a very narrow pH range. Kuroda, therefore, does not teach or suggest an allantoin-containing composition "wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range," as recited by independent claims 1 and 16. Furthermore, Kuroda teaches away from the invention recited in independent claims 1 and 16 by indicating that composition taught by Kuroda are ineffective below a pH of 4.0 and have a reduction in allantoin concentration at pH values between 6-7. Kuroda thus fails to teach or suggest the features of independent claims 1 and 16 and dependent claims 3-5 and 18-22.

Garlen discloses an allantoin containing composition having a pH of "approximately 5." (Col. 4, Ln. 16). Garlen does not teach or suggest stability or effectiveness across any pH range or at any pH values above or below 5. Garlen, therefore, does

not teach or suggest an allantoin-containing composition

"wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range," as recited by independent claims 1 and 16. Garlen thus fails to teach or suggest the features of independent claims 1 and 16 and dependent claims 3-5 and 18-22.

The Office Action states that Grollier "discloses compositions comprising pure allantoin or allantoin in powdered flower, at least one anionic or nonionic surfactant, carboxypolyethylene, cetyl alcohol (emollient), and thickeners such as veegum or carraghenates (a polygalactose)." The Office Action also states that Grollier "does not explicitly teach the instant pH of his final formulations." As such, Grollier does not teach or suggest an allantoin-containing composition

"wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range," as recited by independent claims 1 and 16. Grollier thus fails to teach or suggest the features of independent claims 1 and 16 and dependent claims 3-5 and 18-22.

The combined teachings of Kuroda, Garlen and Grollier fail to provide the features of independent claims 1 and 16 and dependent claims 3-5 and 18-22 as described above. In addition, Kuroda, Garlen and Grollier do not provide the requisite

motivation to combine or modify their teachings to arrive at the invention recited in independent claims 1 and 16 and dependent claims 3-5 and 18-22. In particular, none of the references discloses allantoin-containing compositions "wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range." Thus, it is respectfully submitted that Kuroda, Garlen and Grollier fail to teach or suggest the invention recited in independent claims 1 and 16 and dependent claims 3-5 and 18-22.

Therefore, withdrawal of the rejection of independent claims 1 and 16 and dependent claims 3-5 and 18-22 under 35 U.S.C. § 103(a) is respectfully requested.

Claims 1-4 and 47-50 were rejected as being unpatentable over U.S. Patent No. 4,707,354 to Garlen et al. in view of U.S. Patent No. 4,822,601 to Goode et al. and U.S. Patent No. 4,184,978 to France. Claims 3 and 4 depend from independent claim 1 and claims 49 and 50 depend from independent claim 47.

As discussed above, Garlen discloses an allantoin containing composition having a pH of "approximately 5." (Col. 4, Ln. 16). Garlen does not teach or suggest stability or effectiveness across any pH range or at any pH values above or below 5. Garlen, therefore, does not teach or suggest an allantoin-containing composition "wherein the pH of the

composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range," as recited by independent claim 1. Nor does Garlen teach or suggest an allantoin-containing composition that includes "an acid to adjust the pH range to a range from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range" as recited in independent claim 47.

Garlen thus fails to teach or suggest the features of independent claims 1 and 47 and dependent claims 3, 4, 49 and 50.

The Office Action states, "the compositions of Goode and France do not contain allantoin." Accordingly, neither Goode nor France teaches or suggests an allantoin-containing composition "wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range," as recited by independent claim 1, or an allantoin-containing composition that includes "an acid to adjust the pH range to a range from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range" as recited in independent claim 47. Thus, both Goode and France fail to teach or suggest the features of independent claims 1 and 47 and dependent claims 3, 4, 49 and 50.

The combined teachings of Garlen, Goode and France fail to provide the features of independent claims 1 and 47 and dependent claims 3, 4, 49 and 50. In addition, Garlen, Goode and France do not provide the requisite motivation to combine or modify their teachings to arrive at the invention recited in independent claims 1 and 47 and dependent claims 3, 4, 49 and 50. In particular, none of the references discloses an allantoin-containing composition "wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range" or an allantoin-containing composition that includes "an acid to adjust the pH range to a range from about 3.0 to about 6.0; and wherein the composition is stable and effective over the pH range." Thus, it is respectfully submitted that Garlen, Goode and France fail to teach or suggest the invention recited in independent claims 1 and 47 and dependent claims 3, 4, 49 and 50. Therefore, withdrawal of the rejection of independent claims 1 and 47 and dependent claims 3, 4, 49 and 50 under 35 U.S.C. § 103(a) is respectfully requested.

#### CONCLUSION

For all of the foregoing reasons, it is respectfully requested that the objections and rejections set forth in the Office Action be withdrawn. Applicant submits that claims 1, 3-

PATENT

Attorney Docket No.: 69273-0009

5, 16, 18-22 and 47, 49-53 are allowable over the art of record,  
and that the application is in condition for allowance.

Favorable reconsideration of this application and a timely  
Notice of Allowance are therefore respectfully requested.

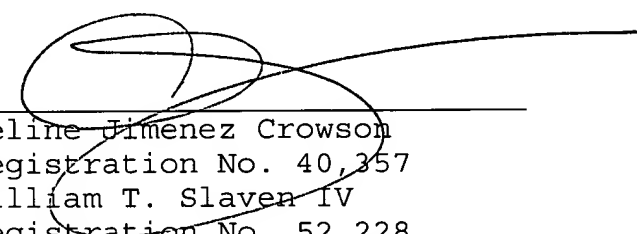
The Examiner is invited to contact Applicant's undersigned  
attorneys by telephone to discuss any matters in order to  
expedite the progress of the present application toward  
allowance.

If there are any other fees due in connection with the  
filing that are not enclosed herewith, please charge any fees or  
credit any overpayment to our Deposit Account No. 50-1349.

Respectfully submitted,

Date: April 15, 2003

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Attachment: Terminal Disclaimer



MARKED-UP COPY OF AMENDED CLAIMS

Please cancel claims 2, 17 and 48 without prejudice or disclaimer.

Please amend claims 1, 16 and 47 as follows:

1. (Amended) A composition comprising an oil-in-water emulsion comprising:

(a) allantoin; and

(b) at least one anionic or nonionic emulsifier that is substantially hydrophilic and is soluble in water;

wherein the pH of the composition is in a range of from about 3.0 to about 6.0; and

wherein the composition is stable and effective over the pH range.

16. (Amended) A composition comprising an oil-in-water emulsion comprising:

(a) allantoin; and

(b) an emulsifier system comprising:

(i) an acidic anionic polymer; and

(ii) an anionic emulsifier that is substantially hydrophilic and is soluble in water[7];

wherein the pH of the composition [being] is adjusted to a range of from about 3.0 to about 6.0; and

wherein the composition is stable and effective over the pH

range.

47. (Amended) A composition comprising an oil-in-water emulsion comprising:

(a) allantoin;

(b) an emulsifier system comprising:

(i) sodium stearoyl lactylate;

(ii) sodium isostearoyl lactylate;

(iii) optionally, triethanolamine;

(iv) optionally, at least one nonionic emulsifier selected from the group consisting of a nonionic emulsifier that is an ethoxylated ether or an ethoxylated ester whose carbon chain length ranges from 8 to 22 carbon atoms; and

(c) an acid to adjust the pH to a range of from about 3.0 to about 6.0;

wherein the composition is stable and effective over the pH

range.